REMARKS

Applicants have amended the claims to more particularly define the invention taking into consideration the Final Rejection and the telephone interview with Examiner O'Hern on July 24, 2008 during which the outstanding rejection was discussed. No agreement on the patentability of the claimed subject matter was reached during the interview. However, it was determined that the best way to proceed was to file an RCE with an amendment in an effort to further clarify the claims and hopefully expedite the prosecution to an early allowance.

Claims 1 and 5 have been amended to specify that the seal is a vulcanisate which is a limitation which was present in claims 28 and 29 which have been canceled as redundant. This is fully supported by the specification, see also page 12, third full paragraph. Claims 1 and 5 have been further amended to remove the "for use" phase, which was entirely appropriate and avoids the use of "which seal" which was rejected as not having antecedent basis thereby obviating this aspect of the rejection. In addition, new claims 37 to 41 have been added to the application to specify metered dose inhalers (MDI) which have specific requirements as they administer pharmaceuticals which must meet FDA requirements. See also page 12 of the present specification wherein it is pointed out that the present invention provides particularly favorable results when used in conjunction with a hydrofluorcarbon propellant in the aerosol device.

It is to be noted and as would be fully appreciated by one of ordinary skill in the art, hydrofluorocarbons are not ozone depleting as are chlorofluorcarbons which have been shown to deplete the ozone layer and were the chief propellant for MDI in the past. However, the physical properties of the hydrofluorocarbons are different from those of ozone depleting cholorfluorocarbons previously approved for use in MDIs. These differences must be taken into consideration in preparing an MDI for meeting FDA requirements including proper dosage. See pages 28 and 29 of the present specification for important features and requirements for MDI and the advantages with respect to the presently claimed invention.

Applicants submit that the claims now present in the application are fully supported by the specification as originally filed and are in full compliance with 35 USC 112.

The rejection of claim1, 5, 28 and 29 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention has been carefully considered but is most respectfully traversed in view of the amendments to the claims and the following comments. The Final Rejection, as interpreted, appears to be the rejection of "which seal" for lack of antecedent basis in claims 1, 5 28 and 29. While it is believed that this term has proper antecedent basis it has been canceled from these claims which obviates this rejection. Accordingly, it is most respectfully requested that this aspect of the rejection be withdrawn.

Applicants most respectfully submit that all of the claims now present in the application are in full compliance with 35 USC 112 and clearly patentable over the references of record.

The rejection of claims 1-5, 9, 12-22 and 28 under 35 U.S.C. 102(b) as being anticipated by Kaszas et al. has been carefully considered but is most respectfully traversed in view of the amendments to the claims and the following comments. In the first instance, it is understood that claim 9 is not included in this rejection in view of the inclusion of the parenthetical phrase, (except claim 9). Moreover, claim 29 is not included in this rejection. The limitation from claim 29 has been included in claim 5 thereby obviating this aspect of the rejection. For the same reason, claim 1 is not anticipated by Kaszas nor are dependent claims 12-20. Moreover, claims 21 and 22 are to a pharmaceutical dispensing device of which there is no disclosure in Kaszas et al. It is most respectfully requested that the portion of the reference which identifies a seal should be included in any further rejection over this reference. Accordingly, for these reasons alone, t this rejection should be withdrawn.

Applicants wish to direct the Examiner's attention to MPEP § 2131 which states that to anticipate a claim, the reference must teach every element of the claim.

> "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently

> described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed.Cir. 1990).

The Official Action suggests that independent claims 1 and 5 lack novelty over US 5,276,094 (Kaszas). Applicants most respectfully submit that it is clear that claims 1 and 5 are directed to seal for a valve for a pharmaceutical dispensing device which includes a metered dose inhalers which must meet strict FDA standards to insure proper operation and free of contamination. Such contamination may come from the seals used in these devices. Kaszas relates to tire inner tubes, air bladders and the like. At column 9, lines 50-55 the use of the vulcanizate as an aerosol spray can linings is described but this is not a seal for a value as presently claimed.

Moreover, an important aspect of the invention is the curing system to produce the claimed vulcanisate which includes the following limitations:

As a cross-linking agent:	*sulphur or a sulphur-donating compound, the cross-linking agent being free of peroxide curing agents.*
As an accelerator:	*a polysulphide compound derived from a substituted dithiocarbonic acid or derivative thereof.*

The Official Action appears to suggest that a polysulphide compound derived from a substituted dithiocarbonic acid is not a "product" feature but instead is a "process" feature which imparts no limitation on claim 1. While a polysulphide compound derived from a substituted dithiocarbonic acid does perhaps indicate some history about the compound, it also imposes a product limitation as would be understood by one of ordinary skill in the art to which the invention pertains. The

polysulphide compound is derived from a substituted dithiocarbonic acid and thus this limits the product in the sense that the claim does not encompass polysulphide compounds derived from an unrelated acid.

Moreover, to reach this conclusion the Official Action seems to have ignored the feature (limitation) in these claims that the accelerator is a polysulphide compound derived from a substituted dithiocarbonic acid. As previously noted, while a polysulphide compound derived from a substituted dithiocarbonic acid does perhaps indicate some history about the compound, it also imposes a product limitation as would be understood by one of ordinary skill in the art to which the invention pertains. The polysulphide compound is derived from a substituted dithiocarbonic acid and thus this limits the product in the sense that the claim does not encompass polysulphide compounds derived from an unrelated acid and is a claim limitation which cannot be ignored.

Moreover, it is urged on page 3 of the Official Action that, "The phrase 'for a valve for use in a pharmaceutical dispensing device' in claim 1, line 1 is not given any patentable weight since the applicant is introducing use limitations into the product claims (see MPEP 2173(q))." This statement is specifically traversed even though the claim has been further amended to no longer use this term. In any case, MPEP §2173(a) is concerned with use claims which intend to claim a process without reciting steps and is not applicable to the present case. Claim 1 is not a method claim but a product claim, and the use described in claim 1 provides context for claim construction and to distinguish over the prior art. The appropriate MPEP section would appear to be MPEP §2111.02 Effect of Preamble. Under the facts of the present case, full weight is to be given to this limitation, which cannot be ignored.

More specifically, Kaszas relates to butyl elastomeric compositions for use in articles requiring low or reduced permeability to gases and improved tear strength, such as tire inner tubes, tire curing bladders and various air bladders (see column 1, lines 6 to 31). The curing system is discussed in column 8, lines 1 to 4, and comprises (I) metal oxide, (ii) sulphur, and (iii) at least one sulphur-based accelerator. Kaszas discloses the following accelerators: thiuram sulphides such as tetramethyl thiuram disulphide (TMTD), thiocarbamates such as zinc dimethyl thiocarbamates (ZDC) and

the thiazyl and benzothiazyl compounds such as mercaptobenzothiazyl disulphide (MBTS) (see column 8, lines 10 to 18). The preferred accelerator is said to be tetramethyl thiuram disulphide (TMTD) (see also column 14, Table VI). The present application acknowledges the use of these known accelerators (see page 2 of the specification, lines 26-35).

As discussed on pages 3 and 4 of the of the present application, it has been found that tetramethyl thiuram disulphide (TMTD) (and also mercaptobenzothiazyl disulphide (MBTS)) is a precursor for the formation of nitrosamines, which are undesirable in seals for pharmaceutical dispensing devices. Thus, the use of these compounds in a curing system for use in the manufacture of a seal for a pharmaceutical dispenser device has this disadvantage (of course, there is no appreciation of this disadvantage in Kaszas since this document is not concerned with pharmaceutical dispenser devices). Furthermore, in most pharmaceutical applications, it is also necessary to extract or wash the cured elastomer in order to remove surface residues and by-products resulting from the cure reaction and moulding process. The aforementioned conventional cure/accelerator systems require relatively lengthy extraction times (typically 50 to 70 hours). Prolonged extraction times have been found to result in a deterioration in material properties.

The present invention solves these problems by the use of a cross-linking system in which:

sulphur or a sulphur-donating compound is used as a cross-linking agent (the cross-linking agent being free of peroxide curing agents), and

a polysulphide compound derived from a substituted dithiocarbonic acid or derivative thereof is used as an accelerator.

It is submitted that there is no teaching or suggestion of such a system in Kaszas. In particular, there is no mention in Kaszas of an accelerator which is a polysulphide compound derived from a substituted dithiocarbonic acid such as xanthic acid. While Kaszas does mention dithiocarbamate compounds, these are salts of dithiocarbamic acid, i.e. NH_2CS_2H. Indeed, the present application acknowledges such accelerators on page 2, line 28 of the description. As will be appreciated, dithiocarbamic acid (NH_2CS_2H) is quite different from dithiocarbonic acid (carbonic acid

is H_2CO_3) and Kaszas is silent regarding polysulphide compounds derived from a substituted dithiocarbonic acid, for example diisopropyl xanthogen polysulphide.

For the sake of completeness it is also pointed out that there is no mention in Kaszas of a seal for a valve for a pharmaceutical dispensing device (notwithstanding that the crosslinking system recited in the claims of the present application is neither taught nor suggested by Kaszas). Furthermore, Kaszas is not concerned with a valve for use in a pharmaceutical dispensing device (as claimed in claim 20), or a pharmaceutical dispensing device (as claimed in claims 21 and 22), or a dispensing apparatus for dispensing pressurised fluid (as claimed in claims 23 to 27).

Accordingly, it is most respectfully requested that this rejection be withdrawn.

The rejection of claims 6-7 and 29 under 35 U.S.C. 103(a) as being unpatentable over Kaszas et al. in view of Simons et al. has been carefully considered but is most respectfully traversed in view of the above comments as applied to Kaszas et al. and the following comments.

Simons relates to a method of making gasketed closure elements for pressurized aerosol containers. This is an unrelated technical field to Kaszas, which is concerned with articles requiring low or reduced permeability to gases and improved tear strength, such as tire inner tubes, tire curing bladders and various air bladders. There would therefore be no motivation for one skilled in the art to combine these references. Simons is also not concerned with seals/valves for use in a pharmaceutical dispensing device. Accordingly, it is most respectfully requested that this rejection be withdrawn.

The rejection of claim 10 under 35 U.S.C. 103(a) as being unpatentable over Kaszas et al. in view of Stevenson et al. has been carefully considered but is most respectfully traversed in view of the above comments as applied to the Kaszas reference and the following comments.

Stevenson relates an article such as an automobile component, for example a tire. An aircraft tire is specifically mentioned. Stevenson is plainly not concerned with seal and valves for use in a pharmaceutical dispensing device. There would therefore

be no motivation for one skilled in the art to look to this reference when faced with the present invention.

The rejection of claim 11 under 35 U.S.C. 103(a) as being unpatentable over Kaszas et al. in view of Blok et al. has been carefully considered but is most respectfully traversed in view of the above comments as applied to the Kaszas reference and the following comments.

Blok relates to EPDM and EPR-based rubber compositions which are vulcanized with peroxide together with a specified combination of sulfur and acrylate co-agents. However, a requirement of claim 1 of the present application is that the cross-linking agent is free of peroxide curing agents. This means that Blok teaches away from the present invention and cannot render the claims obvious.

The rejection of claims 1, 8, 9 and 23-27 under 35 U.S.C. 103(a) as being unpatentable over Klokkers-Bethke et al. in view of Kaszas et al. has been carefully considered but is most respectfully traversed in view of the above comments as applied to the Kaszas reference and the following comments and the amendment to the claims. Claims 28 and 29 are not included in this rejection and since these limitations have been included in claims 1 and 5, this rejection should be withdrawn.

In any case, Klokkers-Bethke relates to a liquid nitroglycerin spray, desirably having a hydrophilic base, and a sealant material for a container having the spray composition therein and which sealant contacts the spray composition, the nitroglycerin absorption value of the sealant being less than 10 mg of nitroglycerin per one gram of sealant material. This is an unrelated technical field to Kaszas, which is concerned with articles requiring low or reduced permeability to gases and improved tear strength, such as tyre inner tubes, tyre curing bladders and various air bladders. There would therefore be no motivation for one skilled in the art to combine these references. Certainly there would be no motivation to replace the seal in Klokkers-Bethke with the elastomer compositions described in Kaszas. There would be no expectation of success since the references pertain to unrelated technical fields. Even if the

references were to be combined, there is no teaching in either document to use an accelerator which is a polysulphide compound derived from a substituted dithiocarbonic acid. As submitted above this is a "product" limitation.

Neither Kaszas nor Klokkers-Bethke is concerned with reducing the formation of nitrosamines, which are undesirable in seals for a pharmaceutical dispensing apparatus such as a pharmaceutical metered does aerosol inhaler device. Neither Kaszas nor Klokkers-Bethke suggests the use of an accelerator which is a polysulphide compound derived from a substituted dithiocarbonic acid in combination with a sulphur cross-linking agent. Nor do Kaszas and Klokkers-Bethke contemplate the advantages of reduced extraction times associated with the use of such an accelerator. Accordingly, it is most respectfully requested that this rejection be withdrawn.

The rejection of claim 9 under 35 USC 112, second paragraph has been obviated by the cancellation of the rejected language from this claim. Therefore, it is most respectfully requested that this rejection be withdrawn.

The rejection of claim 9 under 35 USC 103(a) as obvious over Kaszas et al in view of Stevenson has been carefully considered but is most respectfully traversed in view of the amendments to the claims and the above comments. Kaszas et al does not teach the seal of the claimed invention and Stevenson does not overcome the deficiencies of the primary reference. Accordingly, it is most respectfully requested that this rejection be withdrawn.

The rejection of claim 9 under 35 USC 103(a) as unpatentable over Klokkers-Bethke et al in view of Kaszas et al has been carefully considered but is most respectfully traversed in view of the above comments and further amendments to the claims. Klokkers-Bethke relates to a liquid nitroglycerin spray, desirably having a hydrophilic base, and a sealant material for a container having the spray composition therein and which sealant contacts the spray composition, the nitroglycerin absorption value of the sealant being less than 10 mg of nitroglycerin per one gram of sealant material. This is an unrelated technical field to Kaszas, which is concerned with articles

requiring low or reduced permeability to gases and improved tear strength, such as tyre inner tubes, tyre curing bladders and various air bladders. There would therefore be no motivation for one skilled in the art to combine these references. Certainly there would be no motivation to replace the seal in Klokkers-Bethke with the elastomer compositions described in Kaszas. There would be no expectation of success since the references pertain to unrelated technical fields. Even if the references were to be combined, there is no teaching in either document to use an accelerator which is a polysulphide compound derived from a substituted dithiocarbonic acid. The teaching of the Stevenson reference, not recited in the statement of the rejection does not overcome these insufficiencies and therefore the rejection should be withdraw.

The response to Applicants arguments are noted but are not persuasive for the above reasons. The Examiner's attention is also direct to claims 20, 22, and 37-41 directed to a device contrary to the assertion in the Final Rejection in item 15.

In view of the above comments and further amendments to the claims, favorable reconsideration and allowance of all the claims now present in the application are most respectfully requested.

Respectfully submitted,
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